K003121

OCT 2 0 2000

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

1) Submitter's name, address, telephone number, contact person:

Regulatory Management Services
16303 Panoramic Way
San Leandro, CA 94578-1116
Gary J. Allsebrook
Regulatory Affairs Consultant
Telephone: (510) 276-2648
Fax: (510) 276-3559
Email regman1@home.com

Prepared August 23, 2000

2) Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:

Common/Usual Name:

Diagnostic Ultrasound System and Accessories

Proprietary Name:

MYSONO 201 Diagnostic Ultrasound System and Transducers.

Classification Names:

	FR Number	Product Code
Ultrasound Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX

3) **Identification of the predicate or legally marketed device:**

Medison America, Inc believes that MYSONO 201 Ultrasound system is substantially equivalent to the currently marketed Medison SonoAce 600 (K000030) .

4) **Device Description:**

MYSONO 201:

The MYSONO 201 scanner is a portable, laptop-typed, multiple-mode, and multiple-application ultrasound imaging system. The system contains an ultrasound generator/receiver offering a full complement of conventional operating modes, software-based parameter controls, and recording. The selection of six transducers to be offered with the system permits a wide range of clinical applications including fetal heart, abdomen, OB/GYN, vascular, extremity, pediatric, cardiac, neonatal cephalic, urology. With these general areas of intended use, the various transducers adapt the system for the specific imaging tasks.

Six different models of transducers are available and any two may be connected at the same time. In addition to the initial operational settings for each transducer preprogrammed in the system, user-customized parameter settings for each transducer may be inserted by the operator and stored for recall as needed via the system control panel. Customization includes transmit focusing, filtering, dynamic window curve selection. Controls are also provided to select display format (single and combination) and to utilize cine function

More detailed explanations of these functions and controls are included in the Operator Manual, and in the software/firmware documentation included in this 510(k) Notification. Patient contact materials have been tested for biocompatibility in accordance to their intended use and are described below for each individual transducer. All of the transducers were previously cleared

for use on other Medison Systems.

The MYSONO 201 scanner uses digital beamforming technology. The MYSONO 201 scanner supports a variety of Linear and Convex probes for wide variety of applications. It is an ultrasound scanner, which provides high resolution, high penetration performance, and various measurement functions. Probes are supported in frequencies from 3.5 MHz to 7.5 MHz. These probes can be applied to a variety of fields such as fetal heart, abdomen, OB/GYN, vascular, extremity, pediatric, neonatal cephalic, cardiac, and urology. The MYSONO 201 scanner provides high quality images and various measuring functions. It can measure distances and calculate areas, circumferences and volumes, as well as calculate the date of delivery by using BPD (biparietal diameter), OFD (occipito-frontal diameter), HC (head circumference), AC (abdominal circumference), AD (abdominal diameter), FL (femur length), CRL (crown rump length), APTD (anteroposterior trunk diameter), TTD (transverse trunk diameter), GS (gestational sac), and LMP (last menstral period). Biopsy guidelines are provided on screen to assist in the collection of tissue samples, using biopsy guide adapters offered as an optional accessory. Operating Modes of MYSONO 201 scanner are B, B/B, B/M, and M. The modes of M use the sweep method, which has its images flow from the left to the right. The MYSONO 201 scanner supports the Cine function (capable of storing up to 32 sequential images). Management of patient history is possible by image-storage function. High-resolution images are provided by utilizing a technology called digital dynamic receive focusing. The same clinical uses were cleared for the predicate device(s), Medison SonoAce 600 (K000030, Jan. 4, 2000).

5) **Intended Use**:

- Fetal - OB/GYN
- Abdominal

- Small Organs (breast, thyroid, testicle)
- Pediatric
- Neonatal Cephalic
- Trans-Vaginal
- Trans-Rectal
- Peripheral Vascular
- Cardiac

Typical examinations performed using the system are:

- General abdominal and pelvic studies including organ surveys, assessment, and retroperitoneal cavity studies.
- Study of small parts and superficial structures including breasts, shoulders, thyroid, and the abdominal wall.
- Pediatric scans of organs, superficial, and bony structures.
- Monitoring procedures for infertility studies (other than in vitro fertilization).
- First, second and third trimester pregnancy studies.
- Neonatal head studies.
- Podiatry scans of superficial structures including muscles, tendons and bones.
- General cardiac studies in adults.
- Prostate, bladder and rectum visualization.

6) Technological Characteristics:

This device operates identical to the predicate devices in that piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as a 2D and M-mode images. Scanhead patient contact materials are biocompatible.

The device's acoustic output limits are:

All Applications:

$I_{SPTA.3}$	94 mW/cm2	(Maximum)
MI	1.9	(Maximum)

The limits are the same as predicate Track 1 devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 0 2000

Medison America, Inc.
c/o Mark Job
TUV Product Service Inc.
1775 Old Highway 8 NW, Suite 104
New Brighton, MN 55112-1891

Re: K003121
Trade Name: MYSONO 201 Ultrasound System
Regulatory Class: II
21CFR 892.1560/Procode: 90 IYO
21CFR 892.1570/Procode: 90 ITX
Dated: October 4, 2000
Received: October 5, 2000

Dear Mr. Job:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, ~~and prohibitions against mis~~branding ~~and adulteration~~.

This determination of substantial equivalence applies to the following transducers intended for use with the MYSONO 201 Ultrasound System, as described in your premarket notification:

Transducer Model Number

5.0 MHz 65mm Linear ~~Array Probe~~
7.5 MHz 40mm Linear Array Probe
7.5 MHz 60mm Linear Array Probe
3.5 MHz 60R 60D Curved Array Probe
5.0 MHz 40R 60D Curved Array Probe
6.5 MHz 13R 120D (Endocavity) Curved Array Probe

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Paul M. Gammell, Ph.D. at (301) 594-1212.

Sincerely yours,

for Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

SECTION 4.3

INDICATIONS FOR USE

Ultrasound Device Indications For Use

510(k) Number:
Device Name: **MYSONO 201 Ultrasound System**

Indications for Use: **Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:**

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (B - M)	Other (Specify)
Opthalmic										
Fetal		P	P						P	Note 3
Abdominal		P	P						P	Note 1 Note 3
Intra-Operative (Specify) *(See note 4)*										
Intra-Operative Neurological										
Pediatric		P	P						P	Note 3
Small Organ		P	P						P	Note 3 Note 2
Neonatal Cephalic		P	P						P	
Adult Cephalic										
Cardiac		P	P						P	
Transesophageal										
Trans-Rectal		P	P						P	Note 3
Trans-Vaginal		P	P						P	Note 3
Trans-Urethral										
Intra-Vascular										
Peripheral -Vascular		P	P						P	
Laparascopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others(Specify)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E
Note 1: Abdominal, Solid organs, aneurysms.
Note 2: Small Organ: breast, thyroid, testes.
Note 3: Includes imaging for guidance of biopsy
Note 4: Intra-Abdominal Organs

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003121

Ultrasound Device Indications For Use

510(k) Number:
Device Name: MYSONO 201 Ultrasound System
Transducer: 5.0 MHz/65mm Linear Array Probe

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (B - M)	Other (Specify)
Opthalmic										
Fetal		P	P						P	Note 3
Abdominal		P	P						P	Note 1 Note 3
Intra-Operative (Specify)										
Intra-Operative Neurological										
Pediatric										
Small Organ		P	P						P	Note 2 Note 3
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Vascular										
Peripheral -Vascular		P	P						P	
Laparascopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others(Specify)										

N=new indication; P=previously cleared in K000030, SonoAce600; E=added under Appendix E
Note 1: Abdominal, Solid organs, aneurysms.
Note 2: Small Organ: breast, thyroid, testes.
Note 3: Includes imaging for guidance of biopsy

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003121

Ultrasound Device Indications For Use

510(k) Number:
Device Name: MYSONO 201 Ultrasound System
Transducer: 7.5MHz/40mm Linear Array Probe

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (B - M)	Other (Specify)
Opthalmic										
Fetal										
Abdominal										
Intra-Operative (Specify)										
Intra-Operative Neurological										
Pediatric										
Small Organ		P	P						P	Note 2 Note 3
Neonatal Cephalic		P	P						P	
Adult Cephalic										
Cardiac										
Transesophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Vascular										
Peripheral -Vascular		P	P						P	Note 3
Laparascopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others(Specify)										

N=new indication; P=previously cleared in K000030, SonoAce600; E=added under Appendix E
Note 2: Small Organ: breast, thyroid, testes.
Note 3: Includes imaging for guidance of biopsy

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

David A. Segraves
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003121

Ultrasound Device Indications For Use

510(k) Number:
Device Name: **MYSONO 201 Ultrasound System**
Transducer: **7.5MHz/60mm Linear Array Probe**

Indications for Use: **Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:**

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (B - M)	Other (Specify)
Opthalmic										
Fetal										
Abdominal										
Intra-Operative (Specify)										
Intra-Operative Neurological										
Pediatric										
Small Organ		P	P						P	Note 2 Note 3
Neonatal Cephalic		P	P						P	
Adult Cephalic										
Cardiac										
Transesophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Vascular										
Peripheral -Vascular		P	P						P	
Laparascopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others(Specify)										

N=new indication; P=previously cleared in K000030, SonoAce600; E=added under Appendix E
Note 2: Small Organ: breast, thyroid, testes.
Note 3: Includes imaging for guidance of biopsy

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

David A. Lipman
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003121

Ultrasound Device Indications For Use

510(k) Number:
Device Name: MYSONO 201 Ultrasound System
Transducer: 3.5MHz/60R/60D Curved Linear Array Probe

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (B - M)	Other (Specify)
Opthalmic										
Fetal		P	P						P	Note 3
Abdominal		P	P						P	Note 1 Note 3
Intra-Operative (Specify)										
Intra-Operative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P						P	
Transesophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Vascular										
Peripheral -Vascular										
Laparascopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others(Specify)										

N=new indication; P=previously cleared in K000030, SonoAce600; E=added under Appendix E
Note 1: Abdominal, Solid organs, aneurysms.
Note 3: Includes imaging for guidance of biopsy

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

David A. Ingram
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003121

Ultrasound Device Indications For Use

510(k) Number:
Device Name: MYSONO 201 Ultrasound System
Transducer: 5.0MHz/40R/60D Curved Linear Array Probe

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (B - M)	Other (Specify)
Opthalmic										
Fetal		P	P						P	Note 3
Abdominal		P	N						P	Note 1 Note 3
Intra-Operative (Specify)										
Intra-Operative Neurological										
Pediatric										
Small Organ		P	P						P	Note 2 Note 3
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P						P	
Transesophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Vascular										
Peripheral -Vascular		P	P						P	
Laparascopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others(Specify)										

N=new indication; P=previously cleared in K000030, SonoAce600; E=added under Appendix E
Note 1: Abdominal, Solid organs, aneurysms.
Note 2: Small Organ : breast, thyroid, testes.
Note 3: Includes imaging for guidance of biopsy

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

David A. Seguran
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003121

Ultrasound Device Indications For Use

510(k) Number:
Device Name: MYSONO 201 Ultrasound System
Transducer: 6.5MHz/13R/120D (Endocavity) Curved Linear Array Probe

Indications for Use: **Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:**

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (B - M)	Other (Specify)
Opthalmic										
Fetal										
Abdominal										
Intra-Operative (Specify)										
Intra-Operative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Trans-Rectal		P	P						P	Note 3
Trans-Vaginal		P	P						P	Note 3
Trans-Urethral										
Intra-Vascular										
Peripheral -Vascular										
Laparascopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others(Specify)										

N=new indication; P=previously cleared in K000030, SonoAce600; E=added under Appendix E
Note 3: Includes imaging for guidance of biopsy

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

David A. Lagerwall
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003121